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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/754,826 | 01/04/2001 | Mohamed E. El Halawani | 600.492US1 | 3468 |

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| EXAMINER |
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BELYAVSKYI, MICHAEL A

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,826

Applicant(s)

EL HALAWANI ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-8 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 12/17/04 is acknowledged.

Claims 1-3, 5-8 and 29 are pending.

In view of the amendment, filed 12/17/04 the following rejections remain:

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claim 1-2, 6-8 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (US. Pat. No. 6,369,201, see entire document) for the same reasons set forth in the previous Office Action, mailed 05/05/04.

Applicant's arguments, filed 12/17/04 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) Barker et al. do not teach or suggest claimed immunoconjugate, because the body weights for the group treated with a recombinant myostatin immunoconjugate were not significantly different from the body weights in control groups i.e. the reconstituted myostatin immunoconjugate did not elicit an immune response; (ii) Barker et al., provide no assurance that a myostatin immunogen that is not a peptide would have any effect, much less that a mature myostatin can alter the phenotype of an immunized animal. Moreover, Barker et al. do not specifically mention the mature form of myostatin.

Contrary to Applicant's assertion Barker et al., teach mature forms of vertebrate myostatin, wherein vertebrate myostatin is an avian myostatin, and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier. (see entire document, column 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). It is noted that the instant specification define mature form of myostatin as a full length protein (see page 4 of the instant specification in particular). Barker et al., teach a full vertebrate myostatin polypeptide for example turkey myostatin (SEQ ID NO:35) that is a full length polypeptide of 375 amino acid. (See Fig.1 and column 4 in particular). In Detailed Description, Barker et al. teach that the term "myostatin immunogen" includes polypeptide of myostatin

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molecule, which elicits an immunological response (see column 6, lines 14-25, column 15 lines 1-5, and column 16, lines 42-45). In addition, Barker et al., explicitly teach that administration of a myostatin immunoconjugate results in an increase in body weight (see column 4, lines 15-35 in particular). Moreover, Applicant himself acknowledge that , Barker et al. disclosed a myostatin immunoconjugates capable of eliciting an immune response in a vertebrate subject (see page 4 of Applicant's arguments, 12/29/03 in particular). Barker et al. also teach vaccine composition comprising the myostatin immunoconjugate and pharmaceutically acceptable excipient (Column 4, line 10-15 and column 9, lines 35-50 and column 13, lines 1-65 in particular). In Detailed Description, Barker et al. teach that myostatin molecule is administered in the mix with a pharmaceutically acceptable excipient, such as water, saline, dextrose , glycerol, ethanol. (Column 23, lines 45-65).

Barker et al. also teach that to enhance immunogenicity of myostatin, myostatin immunoconjugate which comprises a fusion polypeptide can be used. (see Column 10, lines 5-10 in particular).

Claim 29 is included because the term "optionally" is interpreted as if the claimed myostatin immunoconjugate does not contain a peptide useful for purification or identification.

The reference teaching anticipates the claimed invention.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al. (US. Pat. No. 6,369,201) in view of Harris et al. (Micron 1999, 30, 597-623) for the same reasons set forth in the previous Office Action, mailed 05/05/04.

Applicant's arguments, filed 12/17/04 have been fully considered, but have not been found convincing.

Applicant asserts neither Barker et al. nor Harris et al. disclosed or suggest a myostatin immunoconjugate, comprising the mature form of vertebrate myostatin linked to the carrier.

Contrary to Applicant's assertion, as has been discussed above, it is the Examiner position that Barker et al. teach mature forms of vertebrate myostatin polypeptide and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier. (see entire document, column 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). Berker at al. further teach that immunological carrier can be any molecule which, when associated with a myostatin immunogen, enhances the immunogenicity of the molecule. (Column 9, lines 22-34).

Barker et al. do not explicitly teach that the carrier is KLH.

However, Harris et al. teach the widespread use of KLH as a hapten carrier and generalized vaccine component that is widely used to enhances the immunogenicity of the vaccine (see Abstract and entire document).

Given the teaching of Harris et al. that KLH is widely used as a carrier to enhance the immunogenicity of the vaccine, one of ordinary skill in the art would have find it obvious to modify the teaching of Barker et al. and substitute carrier described by Barker et al. for KLH carrier to enhances the immunogenicity of myostatin immunoconjugate. One of ordinary skill in the art at the time the invention was made would be motivated to substitute immunological carrier, described by Barker et al. for KLH carrier to enhances the immunogenicity of myostatin immunoconjugate. Finally, given the art recognize widespread use of KLH as a carrier to enhance the immunogenicity, one ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to generate a myostatin immunoconjugate, comprising a myostatin polypeptide linked to KLH as a carrier.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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6. The prior art does not teach or suggest the claimed invention as recited in claim 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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January 26, 2005


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